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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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David H. Gorski

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06/17/2004

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EXAMINER

SAUD, CHRISTINE J

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/755,320	<b>Applicant(s)</b> GORSKI ET AL.	
	<b>Examiner</b> Christine J. Saoud	<b>Art Unit</b> 1647	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 March 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-2, 6, 8-11, 13-16, 18-20, 22-27, 30-31 is/are allowed.
- 6) ☒ Claim(s) 7, 12, 17, 28 and 29 is/are rejected.
- 7) ☒ Claim(s) 3-5 and 21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Surrender of Patent***

The original patent, or a statement as to loss of inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

### ***Claim Amendments***

It is noted that claim 7 was indicated to be an "original" claim and reproduced as "A vector containing the DNA mol of claim 1.". However, this claim was amended at the time the instant application was filed.

### ***Claim Rejections - 35 USC § 112***

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites "the DNA mol of claim 1". This recitation is unclear because there is no "mol" in claim 1. It would appear that "mol" should be "molecule". Correction is suggested. Claims 12, 17, and 29 are indefinite for depending from an indefinite claim.

Claim 28 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

Art Unit: 1647

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record in the previous Office action.

Applicant asserts that the invention is a "novel homeobox gene", therefore, since the homeobox portion of the claimed Gax "gene" comprises nucleotide 749 to nucleotide 931 of SEQ ID NO:1, there is support for this claimed molecule. However, as the claim is currently worded, the claim now encompasses fusion molecules of (1) a DNA encoding either SEQ ID NO:2 or 4 with (2) nucleotides 749 to 931 of SEQ ID NO:1. A fair reading of the specification does not reveal fusion molecules as being contemplated. Even though the claims are read in light of the specification, limitations from the specification cannot be read into the claims and the claims must be given their broadest reasonable interpretation. Therefore, the instant claim appears to be new matter. It is noted that original claim 5 contains language which may make clear that fusion molecules are not the intent of the claimed subject matter (i.e. "comprising a nucleotide sequence having a region which consists of the nucleotide based from X to Y of SEQ ID NO:1"). Amendment of claim 28 to this language ("The DNA molecule of claim 1, comprising a nucleotide sequence having a region which consists of nucleotides 749 to 931 of SEQ ID NO:1") would avoid the instant ground of rejection.

### ***Claim Objections***

Claims 3-5 and 21 are objected to because of the following informalities: they fail to conform with 37 CFR 1.821(d) which requires the format "SEQ ID NO:" when referring to sequences in an application. Appropriate correction is required. It is noted that this formality was not raised in the previous Office action, however, as it does not affect the patentability of the claims, it should not affect the finality of the instant Office action.

### ***Conclusion***

Claims 1-2, 6, 8-11, 13-16, 18-20, 22-27, 30-31 are allowable over the prior art of record.

Applicant is reminded that a new Declaration will be required upon the filing of any claim amendments. Additionally, the application cannot be allowed until the original patent is surrendered (See 37 CFR 1.178).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

Art Unit: 1647

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on mttr, 8:00-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**CHRISTINE J. SAOUD  
PRIMARY EXAMINER**

*Christine J. Saoud*